

REMARKS/ARGUMENTS

This is in response to the Office Action mailed January 4, 2006.

Claims 13, 16-19, 21 and 28 have been withdrawn as being based on non-elected species.

No new matter has been added.

Independent claim 1 and its dependent claims 2-12, 14-15, 20, and 22-23, and independent claim 24 and its dependent claim 25 and independent claim 26 and its dependent claim 27, are currently pending and at issue.

Election - 35 U.S.C. §121

The Examiner asserts that claims 17-20 are generic to a plurality of disclosed patentably distinct species comprising foods and that the Applicant is required to elect a single disclosed species. As the Examiner noted, during a December 20, 2005 telephone conversation to expedite prosecution of the case, Applicants made a provisional election to prosecute the invention of yogurt.

The Applicants affirm the election of the species directed to yogurt. Claims 1-12, 14-15, 22-27 are readable on the elected species. Claims 13, 16-19, 21 and 28 have been withdrawn. Should the examiner find the elected species patentable, it is then respectfully requested that the non-elected species be examined. The Applicants reserve the right to file a divisional application to all subject matter or claims withdrawn, cancelled or restricted out. The Applicants elect these embodiments with traverse.

Claim Rejections - 35 U.S.C. §102

The Examiner has rejected claims 1-12, 14, 15 and 20-27 under U.S.C. § 102(b) as being anticipated by Park (U.S. Patent No. 4,784,871). The Examiner asserts that Park teaches a calcium fortified yogurt and that the claimed printed matter is not a patentable limitation, citing *In re Ngai*, 217 USPQ 401, 404 (Fed. Cir. 2004).

The Applicants disagree with the Examiner's premise that the claimed printed matter is not a patentable limitation. In *Ngai*, which is based on based on *In re Gulack*, 703 F.2d 1381 (Fed. Cir. 1983), the court held that printed matter can be a patentable limitation if the printed matter is functionally related to the claimed product and the content of the printed matter distinguishes the claimed product from the prior art. (See also MPEP section 2112.01, III).

In fact, *Gulack* states that "[d]ifferences between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter." [p. 1358]. It further states that "[u]nder 103, the board cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable..." and that the "claim must be read as a whole." [Id.]

Both the *Ngai* and the *Gulack* decisions indicate that printed matter is a patentable limitation if it defines an article of manufacture and if the printed matter element distinguishes the invention from the prior art in terms of patentability, if the printed matter is functionally related to the product, and if there is a new and unobvious functional relationship between the printed matter and the product.

The present claims include a printed matter element that is functionally related to the product in a new and non-obvious way. Present independent claims 1, 24 and 26, are directed to

an article of manufacture comprising a calcium-containing or dairy product and printed material or a description describing or disclosing a health effect being related to calcium or dairy and selected from the group consisting of one or more of metabolic consumption of adipose tissue, metabolic change, regulation of body weight, weight loss, reduced weight gain, fat loss, and reduced fat gain.

All the claims include a product, either a calcium-containing product or a dairy product, and printed matter, that is functionally related to the product, e.g., calcium and dairy's health effect selected from the group consisting of one or more of metabolic consumption of adipose tissue, metabolic change, regulation of body weight, weight loss, reduced weight gain, fat loss, and reduced fat gain.

The present claims include printed matter that is functionally related to the claimed product and the content of this printed matter distinguishes the claimed product from Park.

Park discloses a calcium fortified yogurt wherein an acid soluble calcium salt is added to fruit flavoring which is subsequently combined with a yogurt base (abstract), which may be effective in preventing or mitigating osteoporosis, and also possibly high blood pressure and colon cancer (column 1, lines 12-14).

Park does not disclose, teach or expressly or impliedly suggest, as set forth in present claims 1, 24 and 26, printed matter describing calcium or dairy's health effect selected from the group consisting of one or more of metabolic consumption of adipose tissue, metabolic change, regulation of body weight, weight loss, reduced weight gain, fat loss, and reduced fat gain. Therefore, Park does not anticipate or render obvious the present claims.

In addition, one skilled in the art would not be motivated to modify or combine Park to

achieve the present invention because prior to the invention recited here, there was no recognition of calcium or dairy's health effect selected from the group consisting of one or more of metabolic consumption of adipose tissue, metabolic change, regulation of body weight, weight loss, reduced weight gain, fat loss, and reduced fat gain. The importance of calcium or dairy's health effect (one or more of metabolic consumption of adipose tissue, metabolic change, regulation of body weight, weight loss, reduced weight gain, fat loss, and reduced fat gain), was previously unrecognized and was unexpected prior to the invention.

Due to these unexpected results, there has been a significant shift in the scientific community and the food industry, which has supported and endorsed the methods of the present invention. The inventive methods have achieved considerable public recognition and commercial success, as indicated by the attached documentation.

Page one of the attached material lists various clinical trials conducted by Dr. Zemel and others further showing the beneficial effects of consuming high calcium and dairy in accelerating the effects of weight loss in humans. Page two shows how the food industry has adopted the novel methods of the present invention. For example, the label "3-A-Day Milk Cheese Yogurt, Burn more fat, lose weight" communicates the message that increasing dairy consumption to at least three servings a day supports weight loss. As set forth on page two, over 50 top U.S. retail chains have licensed the inventive methods and are promoting the inventive methods by placing labels with the weight loss message on over 2.5 billion dairy packages to date. Pages three, four and five evidence various examples of leading industry packages and consumer advertisements. Page six provides testimonials about the inventive methods from notable health professional associations. The American Academy of Family Physicians refers to "dairy nutrition and its contribution to weight

management." The National Medical Association recognizes that "[s]ome of the information that was presented today shows a clear beneficial relationship between the daily intake of three to four servings of dairy products and the reduction of obesity." The American Dietetic Association praises Dr. Zemel's work in that "[i]t has been exciting to see how emerging research on the role of calcium and dairy products adds to the body of knowledge about preventing and treating obesity [and t]his information provides additional tools for dietetics professionals to use in their day-to-day practice."

Applicants further contend that even with widespread recognition, the claimed article of manufacture is so unexpected that there remains skepticism about describing calcium or dairy's health effect selected from the group consisting of one or more of metabolic consumption of adipose tissue, metabolic change, regulation of body weight, weight loss, reduced weight gain, fat loss, and reduced fat gain. For example, there have been advertisements asserting that Yoplait yogurt promotes weight loss (advertising claims that are subject to a license agreement under the present patent application). A challenge was filed by an anonymous party, who argued that there was no support for the claim that calcium consumption promotes weight loss. The challenger apparently doubted the efficacy of the invention as claimed in the present application. The National Advertising Division (NAD) of the U.S. Better Business Bureau ruled that the evidence (research by Dr. Zemel) supported General Mills' advertisement of the weight loss benefits of the calcium-containing dairy product (decision attached). This dispute, and its conclusion accepting the surprising evidence of the weight loss efficacy of calcium, further evidences the non-obviousness of the claimed invention. See also Express Article, published by Express Publications, a subsidiary of the Washington Post Company, 7/19/05, p. 10.

Therefore, Park does not disclose, teach or suggest the claimed invention as set forth in

claims 1, 24 or 26 or dependent claims 2-12, 14-15, 20, 22-23 and 25. These include additional limitations distinguishing them from the cited references, e.g., in claim 2, wherein the description is in the form of printed material; in claim 3, wherein the product is packaged and the description is part of the package; in claim 4, wherein the description directly accompanies the product; in claim 5, wherein the description is imprinted on the product; in claim 6, wherein the description indicates the amounts of calcium contained within the product, and recommended levels of calcium intake for regulation of body weight; in claim 7, wherein the described effects comprise inducing a metabolic change in an individual; in claim 8, wherein the metabolic change comprises decreasing intracellular calcium concentrations ($[Ca^{2+}]_i$), stimulating lipolysis, inhibiting lipogenesis, increasing the expression of white adipose tissue uncoupling protein 2 (UCP2), reducing serum insulin levels, thermogenesis, and/or decreasing the levels of calcitrophic hormones; in claim 9, wherein the described effects comprise reducing or attenuating obesity; in claim 10, wherein the described effects comprise attenuating weight gain and/or adiposity in children; in claim 11, wherein the product comprises a dairy product; in claim 12, wherein the product is yogurt; in claim 14, wherein the product comprises a food fortified with calcium; in claim 15, wherein the product is a dietary supplement; in claim 20, wherein the product is yogurt and the printed material is printed on the yogurt container; in claim 22, wherein the therapeutically effective amount described is at least about 1000 mg/day of calcium; in claim 23, wherein the therapeutically effective amount described is at least about 1346 mg/day of calcium; and in claim 25, wherein the more than suboptimal amount described is at least about 57 portions of dairy per month. Therefore, claims 1-12, 14-15, 20, 22-26 are patentable because the cited reference does not disclose, teach or suggest the present invention.

**Double Patenting
Non-statutory Rejection**

Claims 1-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 8-10 of co-pending Application No. 10/827,301 ("the '301 application").

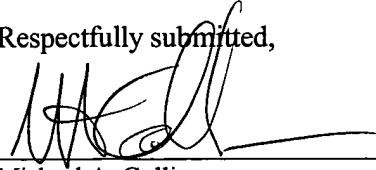
According to MPEP section 804(I)(B)(1), because both applications are filed on the same day, the Examiner will need to determine which application claims the base invention and which application claims the improvement (added limitations). Applicants presume that the Examiner deems the '301 application as the base application. Once the '301 application is allowed or issued, Applicants will at that time file a terminal disclaimer in compliance with 37 CFR 1.321(c), to overcome the rejection in this application.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1-12, 14-15, 20, 22-26 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,



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